

## REMARKS

Claims 1, 2, 6, 7, 9-12, 16, 17 and 19 are pending in this application. By this Amendment, claims 1 and 9 are amended, claims 3-5 and 18 are canceled and new claim 19 is added. Claim 9 is amended to correct a typographical error therein.

No new matter is added to the application by this Amendment. Support for the features added to claim 1 is found in canceled claim 3 and present Example 2 and within the specification, as originally filed, at, for example, the second, forth and fifth paragraphs on page 8, the second full paragraph on page 9, and the first full paragraph on page 13. New claim 19 finds support in present Examples 2 and 4 and within the specification, as originally filed, at, for example, the forth full paragraph on page 8.

### I. Rejections Under 35 U.S.C. §103

#### A. Wanek et al. in view of Quintero et al.

Claims 1-3, 9-11 and 18 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,121,362 to Wanek et al. (hereinafter "Wanek") in view of U.S. Patent No. 6,547,467 to Quintero et al. (hereinafter "Quintero"). This rejection is respectfully traversed.

The Patent Office acknowledges that Wanek fails to teach or suggest radiation sterilization of the separate components within the double-chambered cartridge (see page 2 of the Office Action). The Patent Office introduces Quintero as allegedly remedying the deficiencies of Wanek by teaching that it was known in the art at the time of the invention to package two separate, unmixed components (which include polymerizable and/or crosslinkable monomer and polymerization initiator or accelerator)

within distinct and separate parts of a packaging syringe, wherein the entire assembly is then sterilized with gamma radiation. The Patent Office alleges that (1) it would have been obvious to one of ordinary skill in the art to sterilize the composition of Wanek since Quintero evidences that compositions intended for in vivo use must be sterilized. Moreover, the Patent Office alleges that it would have been obvious to radiation sterilize the components of Wanek within the dual-chambered cartridge of Wanek as Quintero discloses that it was known in the art to achieve a sterile and non-polymerized product using radiation sterilization. Applicants respectfully disagree with these allegations by the Patent Office.

In view of the cancellation of claims 3 and 18, this rejection is moot with respect to those claims.

Wanek fails to teach radiation sterilization as acknowledged by the Patent Office. Quintero is directed to the presentation of adhesives/sealants on biological substrates by means of a micro-applicator. However, nowhere does Quintero teach or suggest use of the adhesives/sealants in dentistry or as moulding materials (hereinafter "MMs") as required by claim 1. In principle, MMs should reproduce the surface structure of the tooth and are not intended to remain on the structure of the tooth. This is a basic difference between the present invention and Quintero's adhesives/sealants. Another difference is Quintero's adhesives can be activated, but need not be activated (i.e., moisture-curing systems) whereas the present invention specifically comprises two-component compounds.

Present claim 1 requires that at least one component of the two components

comprises a polymer having one or more functional groups. The present two-component systems which are suitable for dental moldings consist of polymers with at least one functional group (i.e., vinyl group and SiH groups or OH groups and Si-O alkyl groups in the case of silicone impression materials and aziridino groups in the case of polyether impression materials as recited in new claim 19). The present two-component systems comprises polymers with functional groups because of the desire to be able to remove these polymers intact from the mouth after a short period and the desire that they naturally do not adhere to the tooth substance.

In contrast, Quintero's adhesives adhere to the tooth substance and most importantly only consist of monomers optionally with auxiliary agents. Specifically, Quintero's adhesives are (cyano)acrylate-containing monomers. At best, Quintero teaches gamma radiation sterilization of two separate, unmixed components, namely polymerizable and/or crosslinkable (cyano)acrylate-containing monomers and a polymerization initiator or accelerator, as acknowledged by the Patent Office at page 3 of the Office Action.

Nowhere does Quintero teach or suggest a polymer having one or more functional groups as recited in claim 1. Moreover, nowhere does Quintero teach or suggest subjecting two components, including at least one component comprising a polymer having one or more functional groups, in an unmixed state to radiation sterilization as required by claim 1.

Because Quintero is directed to radiation sterilization of polymerizable and/or crosslinkable monomers and a polymerization initiator or accelerator, a skilled artisan

would not turn to Quintero to modify Wanek's teachings directed to silicone-based impression material. Moreover, even if the skilled artisan modified Wanek with Quintero, the resulting combination would fail to achieve the present invention because Wanek and Quintero fail to teach or suggest radiation sterilization of at least one component of a two component system in an unmixed state which consists of a polymer having one or more functional groups.

Thus, neither Wanek nor Quintero, taken singly or in combination, teaches or suggests the step of subjecting the two components in an unmixed state in a primary packing agent to radiation sterilization, wherein at least one component of the two components comprises a polymer having one or more functional groups and further comprises i) silicone impression materials which are cross-linkable via addition curing or condensation curing reactions, ii) polyether impression materials which are cross-linkable via addition curing or condensation curing reactions or via a cross-linking ring-opening reaction, iii) ring opening polyether impression materials via an aziridino group or iv) polyether impression materials which are cross-linkable by condensation reaction as required in amended claim 1.

Because these features of independent claim 1 are not taught or suggested by Wanek and Quintero, taken singly or in combination, these references would not have rendered the features of claim 1 obvious to one of ordinary skill in the art.

For at least these reasons, claims 1, 2 and 9-11 are patentable over Wanek and Quintero. Thus, withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

**B. Wanek and Quintero in view of Cavezzan**

Claims 6, 7 and 16 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Wanek and Quintero in view of U.S. Patent No. 4,741,966 to Cavezzan. This rejection is respectfully traversed.

The Patent Office acknowledges that Wanek does not specify that the aromatic C<sub>6</sub> – C<sub>12</sub> substituents are diphenyl- or phenyl methyl- siloxane units (see page 3 of the Office Action). The Patent Office introduces Cavezzan as allegedly teaching that it was known in the art at the time of the invention to include either methylphenylsiloxane or diphenylsiloxane units in a two-part dentl impression composition. The Patent Office alleges these particular organosiloxane units are well-known in the art of dental impression materials, the use of such as the aromatic C 6 – C 12 organosiloxanes of Wanek would have been obvious as providing predictable and expected results to one in the art. Applicants respectfully disagree with these allegations.

Cavezzan does not remedy the deficiencies of Wanek and Quintero as described above with respect to independent claim 1, from which claims 6, 7 and 16 directly or indirectly depend.

None of Wanek, Quintero and Cavezzan, taken singly or in combination, teaches or suggests the step of subjecting the two components in an unmixed state in a primary packing agent to radiation sterilization, wherein at least one component of the two components comprises a polymer having one or more functional groups as required by amended claim 1.

Because these features of independent claim 1 are not taught or suggested by

Wanek, Quintero and Cavezzan, taken singly or in combination, these references would not have rendered the features of claim 1 obvious to one of ordinary skill in the art.

For at least these reasons, claims 6, 7 and 16 are patentable over Wanek, Quintero and Cavezzan. Thus, withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

C. Wanek and Quintero in view of Larson et al.

Claims 12 and 17 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Wanek and Quintero in view of U.S. Patent No. 5,540,876 to Larson et al. (hereinafter "Larson"). This rejection is respectfully traversed.

The Patent Office acknowledges that Wanek and Quintero do not a dose of gamma radiation (see page 4 of the Office Action). The Patent Office introduces Larson as allegedly teaching use of gamma radiation for the sterilization of dental impression materials and that a dose of less than 6 megarads (60 kGY) is necessary to avoid cross-linking of the material. The Patent Office alleges that it would have been obvious to employ a dose less than 60 kGY, optimized through routine experimentation, when using the gamma radiation of Quintero to sterilize the composition of Wanek. Applicants respectfully disagree with these allegations.

Larson does not remedy the deficiencies of Wanek and Quintero as described above with respect to independent claim 1, from which claims 12 and 17 indirectly depend.

None of Larson, Quintero and Cavezzan, taken singly or in combination, teaches or suggests the step of subjecting the two components in an unmixed state in a primary

packing agent to radiation sterilization, wherein at least one component of the two components comprises a polymer having one or more functional groups as required in amended claim 1.

Because these features of independent claim 1 are not taught or suggested by Wanek, Quintero and Larson, taken singly or in combination, these references would not have rendered the features of claim 1 obvious to one of ordinary skill in the art.

For at least these reasons, claims 12 and 17 are patentable over Wanek, Quintero and Larson. Thus, withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

**D. Oxman et al. in view of Quintero**

Claims 1, 4, 5 and 9 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,718,577 to Oxman et al. (hereinafter "Oxman") in view of Quintero. This rejection is respectfully traversed.

The Patent Office acknowledges that Oxman does not disclose radiation sterilization of the separate components within a packaging unit (see page 5 of the Office Action). The Patent Office introduces Quintero again and alleges that it would have been obvious to radiation sterilize the components of Oxman within a packaging unit as Quintero discloses that it was known in the art to achieve a sterile and non-polymerized product using radiation sterilization within a primary packaging unit.

Applicants respectfully disagree with these allegations.

In view of the cancellation of claims 4 and 5, this rejection is moot with respect to those claims.

Amended claim 1 incorporates the features of canceled claim 3, which was not rejected under 35 U.S.C. §103(a) as being unpatentable over Oxman in view of Quintero. By failing to reject canceled claim 3 in view of Oxman and Quintero, the Patent Office acknowledges that Oxman and Quintero, taken singly or in combination, fail to teach or suggest the features of amended claim 1.

Thus, Oxman and Quintero, taken singly or in combination, do not teach or suggest the steps of the step of subjecting the two components in an unmixed state in a primary packing agent to radiation sterilization, wherein at least one component of the two components comprises a polymer having one or more functional groups and further comprises i) silicone impression materials which are cross-linkable via addition curing or condensation curing reactions, ii) polyether impression materials which are cross-linkable via addition curing or condensation curing reactions or via a cross-linking ring-opening reaction, iii) ring opening polyether impression materials via an aziridino group or iv) polyether impression materials which are cross-linkable by condensation reaction as required by claim 1.

Because these features of claim 1 are not taught or suggested by Oxman and Quintero, taken singly or in combination, these would not have rendered the features of claim 1 obvious to one of ordinary skill in the art.

For at least these reasons, claims 1 and 9 are patentable over the applied references. Thus, withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

**II. New Claim**

The references of record, taken singly or in combination, further fail to disclose a process according to Claim 1, wherein the at least one functional group is a vinyl group and a SiH group when the at least one component comprises silicone impression materials or an aziridino group when the at least one component comprises polyether impression materials as required by new claim 19.

Thus, Applicants submit that the process recited in claim 19 would not have been obvious to one of ordinary skill in the art in view of the references of record.

**III. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1, 2, 6, 7, 9-12, 16, 17 and 19 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Early and favorable action is earnestly solicited.

**CONDITIONAL PETITION FOR EXTENSION OF TIME**

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit

Account No. 14-1263.

**ADDITIONAL FEE**

Please charge any insufficiency of fees, or credit any excess, to Deposit Account  
No. 14-1263.

Respectfully submitted,  
NORRIS MCLAUGHLIN & MARCUS, P.A.

By /Brian C. Anscomb/  
Brian C. Anscomb  
Reg. No. 48,641  
875 Third Avenue, 18<sup>th</sup> Floor  
New York, New York 10022  
Phone: (212) 808-0700  
Fax: (212) 808-0844